SEP 2 2 2011

510(k) Summary

Submitted by:	Coreleader Biotech Co., Ltd. 19F, No. 100, Sec. 1, Sintai 5th Rd., Sijhih Dist., New Taipei City, Taiwan (R.O.C), 22102 Phone: +886-2-26968880 FAX: +886-2-26968882
Contact Person:	Teeming Tsao
Date Prepared:	May 25, 2011
Proprietary Name:	Coreleader Scar-D Silicone Sheeting
Common Name:	Silicone Sheeting
Classification:	Unclassified
Classification Name:	Elastomer, silicone, for scar management
Predicate Device:	BIODERMIS CORP., K003948, EPI-DERM SILICONE GEL SHEETING SMITH & NEPHEW UNITED, INC., K935803, CICA-CARE SILICONE GEL SHEET
Device Description:	Coreleader Scar-D silicone sheeting is a thin, soft and self-adhesive sheet made from medical grade silicone with a PU Foam/PU non-woven film backing paper and a non-silicone polyester release paper. It is able to hold moisture with adequate pressure on the scar. The sheets are rectangular and come in four sizes, 5 cm x 8 cm, 5 cm x 20 cm, 2.5 cm x 100 cm and 5 cm x 100 cm. They are approximately 0.6 mm thick. The sheet maybe cut

or trimmed to the desired shape or size prior to placement on the scar. The sheets are not for use on an open wound, are not sterile but can be washed.

Intended Use: Coreleader Scar-D Silicone Sheeting is intended for use in the management of closed hypertrophic and keloid scars.

Technological Characteristics: Coreleader Scar-D Silicone Sheeting is a thin, soft and self-adhesive medical grade silicone dressing. It is able to hold moisture with adequate pressure on the scar. Properties of silicone have been observed to hydrate scar tissue, soften it, and therefore aid in reducing the healing time of scars.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Coreleader Biotech Co., Ltd.
% Mr. Ian Li
19 F, No. 100, Sec. 1, Sintai 5th Rd.,
Sijhih Dist., New Taipei City
Taiwan (R.O.C) 22102

SEP 22 2011

Re: K111733
Trade/Device Name: Scar-D Silicone Sheeting
Regulation Number: 21 CFR 878.4025
Regulation Name: Silicone sheeting
Regulatory Class: I
Product Code: MDA
Dated: August 16, 2011
Received: August 30, 2011

Dear Mr. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Bram D. Zuckerman

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):K111733

Device Name: Coreleader Scar-D Silicone Sheeting

Indications for Use:

Coreleader Scar-D Silicone Sheeting is intended for use:

- for the management of closed hypertrophic and keloid scars.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111733